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10/585,629

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Nobuhiro Ito

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EXAMINER

MABRY, JOHN

ART UNIT

PAPER NUMBER

1625

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/585,629	<b>Applicant(s)</b> ITO ET AL.	
	<b>Examiner</b> JOHN MABRY	<b>Art Unit</b> 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 10 April 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☒ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/11/06, 8/10/07</u> .  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Foreign Priority***

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Japan on January 23, 2004. It is noted, however, that applicant has not filed a certified copy of the JP 2004-016075 application as required by 35 U.S.C. 119(b).

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "alkylene" in claim 10 is a relative term which renders the claim indefinite. The term "alkylene" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The term "alkylene" appear on pages 2 and 62 of the Specification and this term is not defined by the Specification. The term "alkyl" is defined by the Specification on page 4, lines 14 - 28 and page 5, lines 1 - 6. The term "alkenyl" is defined by the Specification on page 5, lines 7 - 26. Examiner is not certain as to Applicant's intended definition of the term

Art Unit: 1625

"alkylene". What is Applicant's intended definition of this term as supported by the Specification? Examiner is interpreted the term "alkylene" to be "alkyl" for examination purposes.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for deuteration of an aromatic ring using platinum and palladium, does not reasonably provide enablement for deuteration of an aromatic ring using a combination of catalysts selected from: platinum, palladium, rhodium, iridium, ruthenium, nickel and cobalt – with the exception of platinum/palladium catalyst mixture. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Pursuant to *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988), one considers the following factors to determine whether undue experimentation is required: (A) The breadth of the claims; (B) The nature of the invention; (C) The state of the prior art; (D) The level of one of ordinary skill; (E) The level of predictability in the art; (F) The amount of direction provided by the inventor; (G) The existence of working examples; and (H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure. Some experimentation is not fatal; the issue is

Art Unit: 1625

whether the amount of experimentation is “undue”; see *In re Vaeck*, 20 USPQ2d 1438, 1444.

The analysis is as follows:

(1) Breadth of claims/(2) The nature of the invention: Scope of the method. A method for deuteration of a compound having an aromatic ring comprising the compound having an aromatic ring with a heavy hydrogen wherein the mixed catalyst of not less than two kinds of catalysts selected from palladium, platinum, rhodium, iridium, ruthenium, nickel and cobalt. According to the claimed invention, the method of deuteration claims to use palladium, platinum, rhodium, iridium, ruthenium, nickel and cobalt, simultaneously and in combination thereof.

(3) Level of predictability in the art: It is well established that “the scope of enablement varies inversely with the degree of unpredictability of the factors involved,” and chemical reactivity (which is affected by determinants such as substituent effects, steric effects, bonding, molecular geometry, etc) is generally considered to be an unpredictable factor. See *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970).

(4) Direction or Guidance: That provided is very limited. Applicant shows a general use of deuterating substituted phenyl compounds which substitution is very limited –alkyl, amino, aminoalkyl and hydroxyl.. Pages 53-63 of the Specification describes starting materials and methods for synthesis of compounds wherein the catalyst are platinum

Art Unit: 1625

and palladium and combinations thereof, but does not describe or list all claimed catalysts and substituents on the aromatic compounds as claimed. There is limited evidence in the Specification. Thus, there is no specific direction or guidance regarding said catalysts and claimed substituents specifically mentioned in Scope.

The availability of the starting material and catalysts that is needed to prepare the invention as claimed is at issue here...As per MPEP 2164.01 (b). A key issue that can arise when determining whether the specification is enabling is whether the starting materials or apparatus necessary to make the invention are available. In the biotechnical area, this is often true when the product or process requires a particular strain of microorganism and when the microorganism is available only after extensive screening. The Court *in re Ghiron*, 442 F.2d 985, 991, 169 USPQ 723, 727 (CCPA 1971), made it clear that if the practice of a method requires a particular apparatus, the application must provide a sufficient disclosure of the apparatus if the apparatus is not readily available. The same can be said if certain chemicals are required to make a compound or practice a chemical process. *In re Howarth*, 654 F.2d 103, 105, 210 USPQ 689, 691 (CCPA 1981).

It is not trivial to experimentally interchange any and all of the many substituents and catalysts that exist. As described by F. Zaragoza Dörwald, most organic syntheses fail initially and chemical research is highly inefficient due to chemists spending most of their time "finding out what went wrong and why". Therefore, most syntheses of organic

Art Unit: 1625

compounds are labor-intensive and demanding. Additionally, most final synthetic routes to desired organic molecules are usually very different from initially planned routes. A highly skilled chemist can agree that for many successful organic compounds made, many failures are encountered and experimental repetition is common. This also contributes to the burden and unpredictability of the syntheses of said compounds. (see "Side Reactions in Organic Synthesis: A Guide to Successful Synthesis Design" 2005 Wiley-VCH Verlag GmbH & Co. KGaA, Weinheim.

(6) Working Examples: Applicant shows examples 1-8 (tables on pages 53-62) but no working examples were shown where all claimed catalysts were used and combinations thereof and all aforementioned substituents have been made or used of any kind.

(7) Skill of those in the art: The ordinary artisan is highly skilled, e.g. a masters or PhD level chemist.

(8) The quantity of experimentation needed: Since there are very limited working examples as described above, the amount of experimentation is expected to be high and burdensome.

Due to the level of unpredictability in the art, the very limited guidance provide, and the lack of working examples, the Applicant has not provided sufficient guidance for the artisan to make the invention and would present an undue burden.

MPEP 2164.01(a) states, "A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the

Art Unit: 1625

application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)." That conclusion is clearly justified here.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Kalpala et al (Green Chemistry 2003, 5, 670-676 – already of record) – published as advanced article on web dated September 16, 2003.

Kalpala discloses a method of deuterating 2-methylnaphthalene and eugenol (both aromatic compounds) with a heavy hydrogen as a solvent, more specifically D<sub>2</sub>O, wherein the mixed catalyst of not less than two kinds of catalysts selected from palladium, platinum and nickel. The aromatic compounds disclosed are bonded to alkyl groups.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

Art Unit: 1625

the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-10 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sajiki et al (Synlett 2002, 7, 1149-1151)(PTO-1449) in view of Kozo et al (Bull. Chem. Soc. Japan 1962, 2, 228-232).

The instant application claims a method for deuteration of a compound having an aromatic ring comprising the compound having an aromatic ring with a heavy hydrogen as a solvent, more specifically D<sub>2</sub>O, wherein the mixed catalyst of not less than two kinds of catalysts selected from palladium, platinum, rhodium, iridium, ruthenium, nickel and cobalt. The aromatic compound is bonded to an alkyl group, alkylamino group, or a carboxyl group.

#### ***Scope & Content of Prior Art MPEP 2141.01***

Sajiki et al discloses a method for deuteration of a compound having an aromatic ring comprising the compound having an aromatic ring. naminlgly diphenylmethane,

Art Unit: 1625

with a heavy hydrogen as a solvent, more specifically D<sub>2</sub>O, wherein the catalyst is palladium. The aromatic compound is bonded to an alkyl group and carboxyl group. Deuteration primarily took place on the alkyl chain bonded to the aromatic moiety of the tested substrates – substituted or unsubstituted (see Tables 1 and 2 and entire reference).

Kozo discloses a similar method of deuteration of compounds having an aromatic ring, namingly paraxylene, with deuterium oxide using the following catalysts: nickel, platinum and palladium. Kozo found that nickel exchanges D for H at the methyl groups of the paraxylene and platinum and palladium exchanges D for H at both methyl groups and the benzene ring (see entire reference).

#### ***Differences between Prior Art & the Claims MPEP 2141.02***

The difference between the Sajiki reference and the instant application is Sajiki uses only one catalyst in the reaction mixture for deuteration of an aromatic ring. The instant application claims “not less than two kinds of catalysts” selected from palladium, platinum, rhodium, iridium, ruthenium, nickel and cobalt.

#### ***Prima Facie Obviousness, Rational & Motivation MPEP 2142-2413***

An artisan of ordinary skill would be motivated to combined the prior art references of Sajiki and Kozo to achieved the instantly claimed invention for the following reasons. Sajiki uses only one catalyst in the reaction mixture for deuteration of an aromatic ring which on the alkyl chain bonded to the aromatic moiety of the tested

Art Unit: 1625

substrates. The Kozo reference discloses that use of platinum in a similar process deuterates the hydrogens on the aromatic portion of the substrates. One of ordinary skill would be motivated (obvious to try) the use the references of Sajiki and Kozo in order to achieve deuteration (H-D exchange) at both substituents positions and on the aromatic portions of aromatic ring compounds.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422

Art Unit: 1625

F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-12 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4 and 7-10 of copending Application No. 10/521,531 (most current set of claims dated 6/30/09). Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following.

10/521,531 claims a method for deuterating an aromatic compound comprising and aromatic ring with deuterium as a solvent in the presence of at least one activated catalyst selected from platinum, rhodium, ruthenium nickel and cobalt.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-12 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 and 5-10 of copending Application No. 10/539,188 (most current set of claims dated 8/12/09). Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following.

10/521,531 claims a method for deuterating an aromatic compound of Formula I of R1-X-R2 where R1=aralkyl, X=carbonyl and R2=alkyl deuterium as a solvent in the presence of at least one activated catalyst selected from platinum, rhodium, ruthenium nickel and cobalt.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Conclusion***

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Mabry, PhD whose telephone number is (571) 270-1967. The examiner can normally be reached on M-F from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's primary examiner can be reached at (571) 272-0684, first, or the Examiner's supervisor, Janet Andres, PhD, can be reached at (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Application/Control Number: 10/585,629  
Art Unit: 1625

Page 13

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Examiner  
Art Unit 1625

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